

REMARKS/ARGUMENTS

Claims 1, 3-5, 7-11, 14, and 17-21 were examined. Reexamination and reconsideration of the claims in view of the following remarks are respectfully requested.

Independent claim 1, the only pending independent claim, was rejected as being anticipated by the Zucker '454 application. Such rejection cannot be sustained since Zucker does not teach each and every element set forth in claim 1 herein. Claim 1 reads as follows:

1. *A method for hemostasis of a puncture site in a wall of a blood vessel at an end of a tissue tract having a sheath therein, the method comprising:*
providing a locating member having a proximal end, a distal end, and an expansible member disposed on the distal end thereof,
inserting the locating member through the sheath in the tissue tract so that the expansible member on the locating member enters a lumen of the blood vessel;
expanding the expansible member on the inserted locating member and drawing the inserted locating member proximally so that the expanded expansible member covers the puncture site in the vessel wall;
removing the sheath from the tissue tract while the inserted locating member remains in place;
providing a tubular compression member having a proximal end, a distal end, a central passage between said proximal end and said distal end, and an expansible tissue compression element disposed over the distal portion thereof, and
advancing the tubular compression member over the inserted locating member after the sheath has been removed from the tissue tract so that the locating member is received in the central passage of the tubular compression member and the expansible tissue compression element is located within the tissue tract at a predetermined distance proximal from the wall of the blood vessel to define a tissue compression region; and
expanding the expansible tissue compression element within the tissue tract above the blood vessel wall to apply pressure against subcutaneous tissue and to compress said tissue over the puncture site in the blood vessel wall to promote hemostasis, wherein the expansible tissue compression element on the compression member is left in place until hemostasis has been achieved.

As can be seen, claim 1 requires separate steps of "inserting the locating member through the sheath" and "advancing the tubular compression member over the inserted locating member after the sheath has been removed." Zucker nowhere discloses such steps.

The Examiner argues that Zucker describes a method utilizing “a locating member (ref. 128)” and a “tubular compression member (ref. 102).” Components 102 and 128 of Zucker, however, are in no way equivalent to the separate locating member and tubular compression member of the present invention and are neither intended to nor capable of being used in the claimed methods..

Component 102 of Zucker is the main shaft as shown, for example, in Fig. 3A. Component 128 is the handle which is secured to a proximal end of the main shaft 102. The main shaft 102 has the anchor balloon 124 at its distal end. Thus, if one skilled in the art were to analogize the method and system of Zucker with those of the present invention, the main shaft 102 would most likely be considered the locating member of the present invention. It is the main shaft 102 of Zucker which is placed through the sheath 304 and which is used to position the anchor 124 against the inner wall of the blood vessel lumen.

Zucker, however, fails to disclose any components which are equivalent to the tubular compression member and the expansible tissue compression element of the present invention. Claim 1 requires a tubular compression member having a central lumen and an expansible tissue compression element at its distal end. The central lumen is receivable over the locating member allowing the tubular compression member to be advanced over the locating member.

The handle 128 of Zucker relied on by the examiner is not similar in structure or function to the tubular compression member of the present invention. It is further pointed out that peripheral balloons 150 of Zucker, which the Examiner analogizes to the expansible compression tissue elements attached to the tubular compression member of the present invention, are in fact attached to the same inner member to which the anchor balloon 124 is attached. So, if anything, Zucker teaches that such inflatable members would be attached to the locating member of the present invention, not to a separate tubular compression member as required by claim 1 herein.

As the Examiner is certainly aware, a rejection for anticipation requires that each and every element of the rejected claim be found in the single prior art reference which is being relied on for the rejection. In the present case, Zucker nowhere suggests, much less teaches, that

a tubular compression member having an expansible tissue compression element at its distal end be advanced over a previously inserted locating member which has a separate expansible member at its distal end. As noted above, what Zucker does teach is that a single main shaft 102 is located at the distal end of a tissue tract with an anchor balloon being inflated followed by inflation of the peripheral balloons without any of the balloons being moved relative to each other between inflation steps or at any other time.

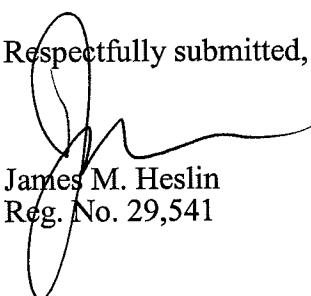
For these reasons, Applicants respectfully submit that the rejection of independent claim 1 for anticipation over Zucker be withdrawn and that claim 1 be allowed. As all other claims are dependent on claim 1, it is further requested that the dependent claims be allowed and that the application be passed to issue at an early date.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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